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Robert L. Stone

Docket: Sa-1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: NARNA SACTIDEV

Serial No.: 10/630,184

Group Art Unit: 1616

Filed: July 30, 2003

Examiner: Frank I. Choi

For: ANTI-WRINKLING COMPOSITION AND AGE REVERSAL COMPLEX

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Mail Stop: Non-Fee Amendment

Commissioner for Patents

P.O. Box. 1450

Alexandria, VA 22313-1450

Honorable Commissioner for Patents:

**DECLARATION UNDER 37 CFR 1.132**

My name is Naina Sachdev.

1. I graduated from Portland State University (Oregon) with B.S. and M.S. degrees with Highest Honors in Mathematics in 1979 and 1980, respectively, and graduated from Chicago Medical School in 1984 with the degree of Doctor of Medicine. Following Internship, Fellowship and Residency periods I qualified to practice as a physician in the State of Oregon since 1991. I currently have an internal and integrative medical practice with emphasis on antiaging medicine and functional medicine. I also have an integrative medical spa with emphasis on internal and external skincare and treatment modalities. Professional societies to which I belong include the American College of Physicians, American Medical Association, Oregon Medical Association, A4M Academy for Anti-Aging, Advancement College for Alternative Medicine and the Institute for Functional Medicine

2. I am the inventor of US Patent Application Serial Number 10/630,186, describing and claiming an alkaline composition containing carnosine or various derivatives of carnosine that is effective in dermatological treatment of skin to reduce or prevent wrinkling.

3. In the development of my invention I was aware of U. S. Patent 5,091,171 to Yu et al which described compositions for dermatological treatment containing alpha hydroxyacid and similar materials in which carnosine could be present in an acidic environment. I undertook to test such compositions in comparison with alkaline carnosine compositions.

The compositions I tested were suspensions as follows:

Composition A-100 mg carnosine and 2 mg  $\alpha$ -hydroxy acid per ml of water (slightly white creamy appearance)

Composition B-100 mg carnosine per ml of water (white creamy appearance)

The pH of Composition A was 5.8 and the pH of composition B was 9.4 (buffered with dimethylaminoethanol).

4. The subjects treated applied to their faces about 1-2 cc of first Composition A twice per day and after ending treatment with Composition A, they applied about 1-2 cc of Composition B to their faces twice per day. The subjects used no other facial compositions other than soap during the period of treatment.

5. Subject 1 was a female, aged 40 years, whose face had fine lines and wrinkles. The subject stopped using Composition A after 4 days of treatment because it caused erythema bilaterally on the cheeks and around the eyes, as well as a burning sensation and skin irritation. The subject then switched to Composition B and after 4 weeks there was dramatic 40% wrinkle reduction around the eyes and the nasolabial folds as well as 30% wrinkle reduction at the upper lip area. The only observed or noticed side effect was a slight tingling sensation that disappeared after 2 days.
6. Subject 2 was a female, aged about 68, whose face had deep wrinkles and "crow's feet" around the eyes and nasolabial fold area as well as the upper lip area. The subject stopped using Composition A after 2 days due to a burning sensation and itching all over her face. The subject then switched to Composition B and after 3 weeks experienced 30% wrinkle reduction around the eyes and the upper lip. There were no side effects observed or noted.
7. Subject 3 was a female, aged about 39, whose face revealed early wrinkling. The subject used Composition A for 1 and one-half weeks but stopped complaining of consistent dry skin. Wrinkle reduction was minimal during this period. The subject then switched to Composition B and after 4 weeks had 30% wrinkle reduction around the eyes and as well as having improved refined skin tone and lasting skin shininess as well as reduced puffiness around the eyes.
8. Subject 4 was a male, aged about 38, whose face revealed early wrinkling. The subject used Composition A for 3 days but stopped because of experiencing skin dryness and itchiness. The subject then switched to Composition B for 3 weeks and had 20% wrinkle reduction around the eyes along with improved skin smoothness. There were no side effects observed or noted.
9. Subject 5 was a female, aged about 60, whose face had a rash and irritation, most prominently on her forehead and cheeks as well as substantial wrinkling around the areas of the eyes and mouth. The subject started using Composition A but reported she stopped after 3 or 4 days but stopped due to the rash becoming aggravated. The subject then switched to

Composition B and after about 4 weeks the rash was resolved and wrinkling reduced by 40% with improved evening of skin tone.

10. Subject 6 was a female, aged about 84, whose face was heavily wrinkled. The subject used Composition A for 2 days but stopped because of experiencing redness and itching around the mouth and the upper cheeks. The subject then switched to Composition B for 4 weeks and had dramatic 35%-40% wrinkle reduction around the eyes and 30% wrinkle reduction on the upper lip. There were no side effects observed or noted.

11. Subject 7 was an adolescent female, aged 16, included in the test to determine possible side effects with young non-wrinkled skin.

Composition A caused redness and heavy itchiness in various parts of the face after 5 days. She then switched to Composition B and experienced no side effects after 3 weeks and, indeed, had acne cleared from her face.

12. On the basis of the foregoing experiments I concluded that an acidic composition containing carnosine was not effective in reducing skin wrinkles as undesirable side effects prevented application of such a composition to facial skin for a sufficient period for reduction in skin wrinkling to be experienced. However, an alkaline composition with carnosine does effectively reduce skin wrinkling without substantial side effects.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements have been made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

6-22-05, 2005

Date

  
Naina Sachdev